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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF	:
MARCO FALCIANI, ET AL.	: EXAMINER: BASICHAS, A.
SERIAL NO: 09/807,413	:
RCE FILED: APRIL 10, 2003	: GROUP ART UNIT: 3749
FOR: BAG FOR PRESERVING AND TRANSPORTING STERILE PRODUCTS IN POWDER FORM AND FOR FORMING SOLUTIONS OF SAID PRODUCTS IN THE BAG	:

REPLY BRIEF

COMMISSIONER FOR PATENTS
ALEXANDRIA, VIRGINIA 22313

SIR:

In response to the Examiner's Answer of July 28, 2004, the present Reply Brief is submitted.

Applicants wish to present the following additional comments to the allowability of the claims over the applied art in view of the comments set forth in the Examiner's Answer of July 28, 2004.

Applicants reiterate that the combination of teachings in the cited art to Sutryn, Herbert, and Gilford do not disclose each of the claimed features.

With respect to claims 6-11, the applicants wish to emphasize that none of the applied art teaches or suggests the claimed features that when the sterile product in powder form and the solvent are mixed, such a solution "only partially fills the capacity of the bag" as recited in independent claim 6, or that "the capacity of the filled bag is larger than the volume of the

ready to use solution after the ready to use solution is reconstituted in the sealed bag" as recited in independent claim 9.

With respect to the above-noted features the Examiner's Answer states:

> The examiner did not believe that the obviousness of leaving room in a bag for the contents to slosh back and forth in, so as to permit a more homogeneous mixture, would require a lengthy explanation. This is especially true in light of the disclosures of Sutryn and Herbert, at least as illustrated by the figures that clearly show a partially filled bag and a bag with a capacity greater than the volume of the solution (see fig. 1 of Sutryn, and see at least figs. 1-4 of Herbert).[1]

In response to that basis for the outstanding rejection, applicants note that in each of Sutryn and Herbert the bag has a certain capacity, i.e. a fixed amount of solvent is desired to be placed in the bag. That is, in both Sutryn and Herbert a fixed amount of solvent is always desired to be placed in the bag, which is the capacity of the bag.

What the outstanding rejection still is not properly considering is that the features in the present invention are not merely directed to leaving an incidental amount of room in a bag for contents to "slosh back and forth".

In the present invention, by designing a bag to be only partially filled, different numbers of doses of ready to use solution can be made and stored in the bag. That is, the structure of the claimed bag allows different amounts of powder to be initially placed in the bag, and combining that with the fact that different amounts of solution can be introduced into the bag (because of the oversizing of the bag), multiple doses of the ready to use solution can be reconstituted in the bag. As an example, based on the amount of sterile powder initially placed in the bag and the amount of solvent introduced into the bag, the bag can contain 1, 5, 10, etc. doses of the ready to use solution, which can be easily distributed.

[1] The Examiner's Answer of July 28, 2004, page 7, lines 12-18.

In both Sutryn and Herbert the bag essentially has one capacity for which it is to be filled because the same amount of powder is introduced into the same amount of solvent in the bag.

Stated another way, in both Sutryn and Herbert the bag is filled to capacity as it has the maximum amount of solvent designed for the bag. That is not the case in the claimed invention in which the bag can have significantly less solvent introduced therein than the maximum amount of solvent that can be put in the bag, i.e. in the present invention the solvent is not filled up to the capacity of the bag. That is clearly not the case in Sutryn and Herbert.

With respect to claims 12-25, those claims even further distinguish over the applied art. Claims 12-25 require a step of ***feeding solution into a bag containing a dosed amount of soluble sterile product to give a solution of a predetermined concentration***, and then removing individual dose sizes from the bag. Such features clearly distinguish over the applied art.

Both Sutryn and Herbert disclose an operation in which a bag initially contains a solvent and a powdery substance is then introduced into the bag to create the solution. Such features are directly contrary to the operations in claims 12-25.

With respect to such features, the Examiner's Answer states:

> As discussed above, it would be readily apparent from a cursory glance at the illustrations of Sutryn and Herbert that the compartment mentioned by appellants constitutes a part of the bag and thereby contained therein. In addition, Herbert makes specific mention to the order in which the components are introduced (see at least col. 2, lines 37-61) and makes it clear that the powder is "first" and that the "aqueous solution or carrier solution is then filled".[2]

The above-noted basis for the outstanding rejection improperly considers the claim limitations relative to the teachings in Herbert and Sutryn.

[2] Examiner's Answer of July 28, 2004, page 9, line 16, to page 10, line 2.

First, the basis for the outstanding rejection appears to indicate that merely putting a powder in a separate compartment from a solvent in Herbert and Sutryn meets the claim limitations. However, claims 12-25 require more than such a teaching. To that extent, Herbert clearly discloses at col. 2, lines 37-61 an operation of first putting a powder into its own compartment and then putting the solution into its own compartment, but Herbert specifically states "there is no risk that any liquid enters into the first chamber and thus destroys the powdery material" (Herbert at col. 2, lines 59-61). Herbert goes on to then note, in a portion not cited in the rejection, that after the container is finally formed the compartment with the powder is broken "so that the powdery or liquid medicant slips downward into the second chamber [the chamber containing the solvent] without any additional operations being required and, what is most important, under sterile conditions" (Herbert at col. 3, lines 17-21).

Applicants note that the claimed features are not directed to such an operation in Herbert, which is also believed to be similar to the operation in Sutryn, of initially forming a bag device with solvent in one chamber and powder in another. In claims 12-25 the feeding operation is a feeding operation of the solvent into the bag to ***give a solution of a predetermined concentration***. That operation would only correspond to the operations in Herbert and Sutryn in which the powder is released from its chamber into the chamber containing the solvent. The basis for the outstanding rejection is clearly not fully considering ***all*** of the claim limitations.

Stated another way, in Herbert and Sutryn forming a bag device with powder in one compartment and solvent in another does not correspond to the claimed operation of ***feeding solvent into a bag to give a solution of a predetermined concentration***. In Herbert and Sutryn the powder is introduced into the solvent (by releasing the powder from its own compartment) to give a solution of a predetermined concentration, which again is in direct

contrast to the claimed features. With respect to claims 12-25, for example claim 12, the basis for the outstanding rejection is not properly considering the limitation of "feeding into the bag...to ***give a solution of a predetermined concentration***, an amount of solvent...". As the outstanding rejection has not considered all of the claimed features, the outstanding rejection is clearly improper with respect to claims 12-25 in the above-noted matter.

Applicants also reiterate comments that the Gilford reference is nonanalogous to Sutryn and Herbert. The basis for the outstanding rejection appears to misinterpret applicants' arguments on that point. Applicants are not arguing that Gilford is nonanalogous to the claims, although that is the case, but applicants note that the teachings in Gilford are irrelevant to Sutryn and Herbert with which such teachings in Gilford are being combined. Gilford is directed to a sample processing container that can store samples that must be evaluated, and therefore removed. Gilford is not at all directed to a device that may contain a "single dose" as Gilford is not directed to storing a solution that is to be applied to a patient in dosages.

Neither Sutryn nor Herbert teach any operation in which the contents of the bags therein should be taken out in sample sizes as in Gilford, or for that matter individual dosages as required in the claims.

Stated another way, as neither Herbert or Sutryn are directed to a device to contain samples or why would one of ordinary skill in the art utilize the teachings in Gilford in such devices. The only motivation set forth in the Examiner's Answer to make such a combination of teachings is "for the purpose of sampling the contents of the bag"[3] (apparently the contents in the bags in Sutryn and Herbert). However, such a motivation is nonsensical as Herbert and Sutryn do not disclose contents to be sampled. Gilford discloses removing samples from a bag because Gilford discloses a bag containing samples. Herbert

[3] The Examiner's Answer of July 28, 2004, page 5, lines 3-4.

and Sutryn do not disclose any such feature, and thus it is nonsensical to suggest that one of ordinary skill in the art would apply the teachings in Gilford of a bag including samples that are designed to be removed in small quantities to the teachings in Sutryn and Herbert that are not even directed to a bag with samples.

For the foregoing reasons, applicants respectfully reiterate that each of claims 6-25 clearly distinguish over the applied art.

With respect to dependent claims 7, 10, 18, 19, 23, and 25, applicants also again reiterate that the basis for the outstanding rejection has essentially ignored the limitations therein. In that respect, applicants note that neither Sutryn nor Herbert disclose any feature of making a bag 1.5 to 2 times a volume of a reconstituted ready to use solution. To summarily dismiss such a limitation as in the outstanding rejection is believed to be clearly improper. Given that the device of the present invention and the device of Herbert and Sutryn have completely different objectives, and considering that making the capacity of the bag 1.5 to 2 times the volume of a reconstituted ready to use solution allows the device of the present invention to beneficially achieves its objectives, summarily dismissing such a limitation as an optimal workable range of the structures in Herbert and Sutryn is clearly improper.

For such reasons, dependent claims 7, 10, 18, 19, 23, and 25 are believed to further distinguish over the applied art.

With respect to dependent claims 8, 11, 13, 15, 17, 21, and 24, applicants reiterate that none of the applied teaches or suggests that the volume of the ready to use solution reconstituted in the bag is "a multiple of single doses of ready to use solution directly usable for practical utilization", and thus those claims further distinguish over the applied art.

In that respect, the basis for the outstanding rejection does not even appear to be properly considering the word "dose". Webster's New College Dictionary defines dose as " a specified amount of a therapeutic agent prescribed to be taken at one time or at stated

intervals".[4] If the Examiner is utilizing a different definition of the word "dose", it is respectfully requested that be clearly stated on the record how the Examiner is defining the word "dose". Clearly, Gilford does not teach or suggest anything similar to a dose. Removing a sample in Gilford is clearly not a dose. Thus, clearly, Gilford does not disclose or suggest removing anything even closely resembling "multiple single doses".

For such reasons, dependent claims 8, 11, 13, 15, 17, 21, and 24 even further distinguish over the applied art.

For the foregoing reasons, applicants respectfully submit that each of the claims is allowable and that the outstanding rejection must be REVERSED.

Respectfully submitted,

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[4] A copy of that definition from the noted dictionary is attached hereto.

Webster's II

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...for wiping the shoes. 2. *Slang.* One who unprotestingly allows mistreatment by others.

door·nail (dôr′nāl′, dōr′-) *n.* A large-headed nail once used as a stud ... **—dead as a doornail.** Undoubtedly dead.

door·post (dôr′pōst′, dōr′-) *n.* A doorjamb.

door prize *n.* A lottery prize awarded to the holder of a ticket purchased at or before a function.

door·sill (dôr′sĭl′, dōr′-) *n.* The threshold of a doorway.

door·step (dôr′stĕp′, dōr′-) *n.* A step leading to a door.

door·stop (dôr′stŏp′, dōr′-) *n.* 1. A wedge inserted beneath a door to hold it open at a desired position. 2. A weight or spring that prevents a door from slamming. 3. A rubber-tipped projection attached to a wall to protect it from the impact of an opening door.

door-to-door (dôr′tə-dôr′, dōr′tə-dōr′) *adj.* Making or being unsolicited calls from one house to another in an area <a *door-to-door* salesman> **—door′-to-door′** *adv.*

door·way (dôr′wā′, dōr′-) *n.* The entrance to a room or building.

door·wom·an (dôr′wo͝om′ən, dōr′-) *n.* A woman employed to attend the entrance of a hotel, apartment house, or building.

door·yard (dôr′yärd′, dōr′-) *n.* A yard in front of the door of a house.

doo·zy *or* **doo·zie** (do͞o′zē) *n., pl.* **-zies.** [Poss. blend of DAISY and DUESENBERG, a luxury car of the late 1920's and 1930's.] Something extraordinary or bizarre.

do·pa (dō′pə) *n.* [Contraction of E. *dihydroxyphenylalanine.*] An amino acid, $C_9H_{11}NO_4$, that is converted to dopamine in the blood-stream and used to treat Parkinson's disease.

do·pa·mine (dō′pə-mēn′) *n.* [DOP(A) + AMINE.] A monoamine neurotransmitter that is a carboxylated form of dopa and is essential to normal nerve activity.

dopant (dō′pənt) *n.* [DOP(E) + -ANT.] A small quantity of a substance, as phosphorus, that is added to another substance, as a semiconductor, to alter the latter's properties.

dope (dōp) *n.* [Du. *doop,* sauce < *doopen,* to dip.] 1. A viscid substance or liquid, esp. a lubricant such as axle grease or an absorbent material such as the nitroglycerin used to make dynamite. 2. A preparation resembling varnish formerly used to protect, waterproof, and tighten the cloth surfaces of airplane wings. 3. *Informal.* A narcotic, esp. one that is addictive. 4. A narcotic used to alter the performance of a racehorse. 5. *Slang.* A very stupid person. 6. *Slang.* Factual, esp. confidential, information. **—*v.* doped, dop·ing, dopes.** *—vt.* 1. To add dope to. 2. *Informal.* To administer a narcotic to. 3. *Informal.* To figure out (an outcome or puzzle). 4. *Informal.* To make a rough sketch of. *—vi. Informal.* To take drugs. **—dop′er** *n.*

dope sheet *n. Slang.* A publication giving information on the horses running in the day's races.

dope·ster (dōp′stər) *n.* One who analyzes and predicts future events, as in sports or politics.

dop·ey *also* **dop·y** (dō′pē) *adj.* **dop·i·er, dop·i·est** *Slang.* 1. Sluggish or lethargic from or as if from drugs. 2. Stupid. 3. Foolish.

dop·pel·gäng·er *or* **dop·pel·gang·er** (dŏp′əl-gäng′ər, dōp′əl-gang′ər) *n.* [G. : *doppel,* double + *gänger,* goer < *gehen,* to go.] A double of a living person, esp. one that haunts its own counterpart.

Dop·pler (dŏp′lər) *adj.* Of, relating to, or utilizing the Doppler effect in radar.

Doppler effect (dŏp′lər) *n.* [After Christian Johann *Doppler* (d. 1853).] An apparent change in the frequency of waves, as of sound or light, when the source and observer are in motion relative to one another, the frequency increasing when the source and observer approach one another and decreasing when they move apart.

Doppler radar *n.* Radar that uses the Doppler effect to measure velocity.

dopy (dō′pē) *adj. var. of* DOPEY.

Do·ra·do (də-rä′dō) *n.* A constellation of the Southern Hemisphere near Reticulum and Pictor.

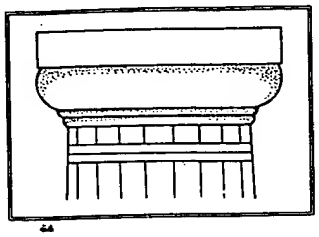
dor·beet·le (dôr′bēt′l) *n.* [Obs. *dor,* a buzzing bee or beetle (< ME *dore* < OE *dora*) + BEETLE.] An Old World dung beetle, *Geotrupes stercorarius,* that makes a droning sound in flight.

Dorcas society (dôr′kəs) *n.* [After *Dorcas,* a Christian woman of Joppa in the 2nd cent. A.D.] A women's auxiliary group, often sponsored by a church, that provides clothes for the poor.

Dor·ian (dôr′ē-ən, dōr′-) *n.* One of a Hellenic people that invaded Greece around 1100 B.C. and remained culturally and linguistically dominant within the Greek world, esp. in Sparta, Corinth, and Argos. *—Dor′i·an adj.*

Doric (dôr′ĭk, dŏr′-) *n.* [Lat. *Doricus* < Gk. *Dorikos* < *Doris,* a region of ancient Greece.] A dialect of ancient Greek spoken in the Peloponnesus, Crete, certain of the Aegean islands, Sicily, and in southern Italy. *—adj.* 1. Of, pertaining to, typical of, or designating Doric. 2. Designating or in the style of the Doric order.

Doric order *n.* The oldest and simplest of the three orders of classical Greek architecture, marked by heavy, fluted columns having no base and plain saucer-shaped capitals.



Doric order

Dor·king (dôr′kĭng) *n.* [After *Dorking,* a town in England.] A domestic fowl of a breed with a heavy body, raised mainly for the table.

dorm (dôrm) *n. Informal.* A dormitory.

dor·mant (dôr′mənt) *adj.* [ME *dormaunt* < OFr. *dormant* <pr.part. of *dormir,* to sleep < Lat. *dormire.*] 1. Asleep or inactive. 2. Latent but capable of being activated <"a harrowing experience which . . . lay *dormant* but still menacing" —Charles Jackson> 3. Temporarily quiescent, as a volcano. 4. *Biol.* Being in a relatively inactive or resting condition in which some processes are slowed down or suspended. **—dor′man·cy** *n.*

dor·mer (dôr′mər) *n.* [OFr. *dormeor,* bedroom < *dormir,* to sleep < Lat. *dormire.*] 1. A window set vertically in a small gable projecting from a sloping roof. 2. The gable holding a dormer.

dor·mie (dôr′mē) *adj. var. of* DORMY.

dor·min (dôr′mĭn) *n.* [DORM(ANCY) + -IN.] Abscisic acid.

dor·mi·to·ry (dôr′mĭ-tôr′ē, -tōr′ē) *n., pl.* **-ries.** [Lat. *dormitorium* < *dormitorius,* of sleep < *dormire,* to sleep.] 1. A room furnished with beds for a number of persons. 2. A structure for housing a number of persons, as at a school. 3. A suburban community whose residents commute to a nearby metropolis for employment and recreation.

dor·mouse (dôr′mous′) *n.* [ME *dormowse.*] Any of various small, squirrellike Old World rodents of the family Gliridae.

dor·my *also* **dor·mie** (dôr′mē) *adj.* [Orig. unknown.] Ahead of an opponent by as many holes in a golf match as remain to be played.

dor·nick[1] (dôr′nĭk) *n.* [ME *dornick,* after *Doornik* (Tournai), Belgium.] A coarse damask cloth.

†dor·nick[2] (dôr′nĭk) *n.* [Perh. of Celtic orig.] *Regional.* A small chunk of rock : STONE.

do·ron·i·cum (də-rŏn′ĭ-kəm) *n.* [NLat. < Ar. *dorūnaj.*] A plant of the genus *Doronicum,* which includes the leopard's-bane.

dors– *pref. var. of* DORSO-.

dor·sad (dôr′săd′) *adv. Anat.* In the direction of the back.

dor·sal (dôr′səl) *adj.* [LLat. *dorsalis* < Lat. *dorsualis* < *dorsum,* back.] 1. *Anat.* Of, toward, on, in, or near the back. 2. *Bot.* Of or on the outer surface, underside, or back of an organ. **—dor′sal·ly** *adv.*

dorsal fin *n.* The main fin on the dorsal surface of fishes or certain marine mammals.

Dor·set Horn (dôr′sĭt) *n.* [After *Dorset,* a county in England.] A long-horned domestic sheep of a breed with fine-textured wool.

dorsi– *pref. var. of* DORSO-.

dor·si·ven·tral (dôr′sĭ-vĕn′trəl) *adj.* Having distinct upper and lower surfaces.

dorso– *or* **dorsi–** *or* **dors–** *pref.* [< Lat. *dorsum,* back.] 1. Back <*dorsad*> 2. Dorsal <*dorsoventral*>

dor·so·ven·tral (dôr′sō-vĕn′trəl) *adj.* [DORSO- + VENTRAL.] Extending from a dorsal to a ventral surface.

dor·sum (dôr′səm) *n., pl.* **-sa** (-sə) [Lat., back.] *Anat.* 1. The back. 2. A part of an organ or appendage analogous to the back.

do·ry[1] (dôr′ē, dōr′ē) *n., pl.* **-ries.** [Mosquito *dōri,* dugout.] A small, narrow, flat-bottomed fishing boat with high sides and a sharp prow.

do·ry[2] (dôr′ē, dōr′ē) *n., pl.* **-ries.** [ME *dorre* < OFr. *doree,* gilded, fem. p.part. of *dorer,* to gild < LLat. *deaurare* : Lat. *de-.* (intensive) + Lat. *aurum,* gold.] 1. The John Dory. 2. WALLEYE 3.

DOS (dŏs, dôs) *n.* [D(ISK) O(PERATING) S(YSTEM).] *Computer Sci.* An operating system that resides on a disk.

dos-à-dos (dō′zä-dō′) *n., pl.* **dos-à-dos** (-dōz′, -dō′) [Fr. : *dos,* back + *à,* to + *dos,* back.] A sofa or carriage accommodating two people seated back to back.

dos·age (dō′sĭj) *n.* 1. a. Administration of a therapeutic agent in prescribed amounts. b. Determination of the amount to be administered. c. DOSE 1. 2. Addition of an ingredient to a substance, esp. to wine, in a specific dose.

dose (dōs) *n.* [Fr. < LLat. *dosis* < Gk. < *didonai,* to give.] 1. A specified amount of a therapeutic agent prescribed to be taken at one time or at stated intervals. 2. *Med.* The amount of radiation administered to a certain bodily part. 3. *Informal.* A portion of an experience, esp. of something unpleasant, to which one is subjected <a *dose* of misfortune> 4. An ingredient added, esp. to wine, to impart flavor or strength. 5. *Slang.* A venereal infection. *—vt.* **dosed, dos·ing, dos·es.** 1. To give a dose to, as of medicine. 2. To give or prescribe (medicine) in doses. **—dos′er** *n.*

do-si-do (dō′sē-dō′) *n., pl.* **-dos.** [Var. of DOS-À-DOS.] 1. A square-dance movement in which two dancers approach each other and circle